

Remarks

Applicants have received and reviewed the Office Action dated June 22, 2009. Applicants request entry of this Amendment and reconsideration of the rejection of the claims.

Applicants have cancelled claims 5-7 without prejudice. Applicants reserve the right to pursue the subject matter of these claims in one or more continuation applications.

Claims 1 and 8 have been amended. Claim 1 has been amended to incorporate claim 7. Claim 8 has been amended to change the dependency as a result of cancellation of a claim. These amendments do not present any issues not previously considered by the Examiner.

35 U.S.C. § 112

Claim 7 is rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants have cancelled this claim rendering the rejection of this claim moot. Applicants request withdrawal of this rejection.

35 U.S.C. § 103(a)

Claims 1-8 and 10-13 were rejected under 35 U.S.C. § 103(a) over *Rockey*, US 4,763,653 in view of *Stack et al.*, US 2003/0199991. Claims 5-7 are cancelled rendering the rejection of these claims moot. Applicants traverse this rejection with respect to claims 1-4, 8, and 10-13.

The recent Supreme Court case, *KSR Int 'I Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1734 (2007), sets forth the legal standard for obviousness. This case reaffirms the analytical framework set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), which mandates that an objective obviousness analysis includes: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; and (3) resolving the level of ordinary skill in the pertinent art. *Id.* at 1734. Secondary considerations such as commercial success, long felt but unsolved needs, or failure of others may also be persuasive.

In rejecting claims under 35 U.S.C. § 103(a), the examiner bears the initial burden of establishing a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Only if this initial burden is met does the burden of coming forward with evidence or argument shift to the appellant. *Id.* at 1445. Obviousness is then determined on the basis of the

evidence as a whole and the relative persuasiveness of the arguments. *See Oetiker*, 977 F.2d at 1445. One criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that claimed subject matter should be carried out and would have a reasonable likelihood of success viewed in light of the prior art. *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

"It remains important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does". *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). "Hindsight" is inferred when the specific understanding or principal within the knowledge of one of ordinary skill in the art leading to the modification of the prior art in order to arrive at appellant's claimed invention has not been explained. *In re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). The claimed subject matter is nonobvious if it involves a number of complex and unpredictable alternatives and there is no reason one of skill in the art would select one alternative over another. *Ortho-McNeil vs. Mylan, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

Applicants claim 1 is directed to an implantable gastro-intestinal device comprising: a gastric bypass comprising an inlet and an outlet and comprised of a permeable material; an inflatable chamber comprising an expandable asymmetric toroidal shaped chamber attached to the gastric bypass and located proximate to the inlet of the gastric bypass, wherein the toroidal chamber holds the inlet in an open configuration when the toroidal chamber is inflated; an esophageal extension comprising one or more flaps, and attached to the inlet of the gastric bypass, wherein food passes into the gastric bypass through the esophageal extension; a small bowel extension attached to the outlet of the gastric bypass and comprised of a permeable material, wherein the small bowel extension receives material exiting the outlet of the gastric bypass.

Applicants submit that the combination of the references does not disclose all of the elements of the claims, and there would be no reasonable expectation of success.

The Rockey et al reference does not disclose a gastric bypass comprised of a permeable material; an expandable asymmetric toroidal shaped chamber attached to the gastric bypass and located proximate to the inlet of the gastric bypass; and an esophageal extension comprising one or more flaps, wherein the esophageal extension is attached to the inlet of the gastric bypass. The sleeve of the Rockey et al reference is "impervious to both gastric secretions and food substances". See col.2, lines 5-10. Any of the expandable balloons described by Rockey et al are not described as asymmetrical toroidal shaped or as attached to the sleeve proximate to the inlet of the gastric by pass. Rockey indicates the balloons are removable. See col. 9 lines 5-10. Rockey et al does not describe an esophageal extension at all.

The deficiencies of Rockey et al are not remedied by reference to Stack. Stack also does not describe a gastric by pass comprised of a permeable material. The Stack patent application indicates that that the bypass portion is constructed of a polymeric material that prevents contact of the food with the walls of the antrum. See para [0038] In addition, Stack et al does not describe an expandable chamber that is asymmetrically toroidal in shape. An expandable chamber of Stack et al is not described or shown as asymmetrically toroidal. The Stack et al reference does not describe an esophageal extension that comprises one or more flaps. The extension of Stack et al is described as stent like and present for the purposes of alignment. See para[0071].

Thus, this combination of references does not disclose all of the elements of the claims.

Applicants submit that one of ordinary skill in the art would not have a reasonable expectation of success in obtaining the claimed device from the disclosure of Rockey et al in combination with Stack. There are just too many variables that have to be changed from the device described in Rockey and Stack in order to obtain the claimed device with no direction or guidance suggested by either reference as to which of many options to select.

Moreover, both the Rockey et al patent and Stack patent application specify that at least a portion of the device be impermeable. One of the objectives of the device of Rockey et al. is to

isolate the walls of the stomach from fluids flowing into it by fluid tight engagement with the stomach wall. See col. 4, lines 8-14 and col.4, line 63 to col. 5, line 12. One of the objectives of the small bowel extension of Stack is to prevent food and digestive juices from contacting the mucosa of the duodenum. If the devices of Rockey et al and Stack were permeable they would not function to isolate the stomach wall or prevent digestion of the contents passing through the device. Thus, applicants submit that the disclosure of Rockey et al in combination with Stack does not provide a reasonable expectation of success of obtaining the claimed subject matter.

In addition, neither of the cited references describes an asymmetric toroidal shaped expandable chamber. Neither reference discusses the issue of twisting of the gastric bypass. In fact, this is not a consideration of the gastric device of Rockey et al, as Rockey et al teaches that the device is expanded into a tight sealing arrangement with the interior surface of the stomach. Likewise, the devices of Stack are for the most part shown in tight adherence to the wall of the antrum. There is no discussion in this reference of the need or desire to minimize twisting of the bypass. Thus, there would be no reason for the device of Rockey et al or that of Stack et al to utilize an asymmetric toroidally shaped chamber.

Finally, neither of the references describes an esophageal extension comprising one or more flaps. The Rockey et al reference does not describe any esophageal extension. The Stack et al reference only describes such an extension as a stent and for the purposes of alignment. There is no discussion in either reference of the need to prevent reflux back into esophagus. Thus, there would be no reason for the device of Stack to include flaps as there is no discussion in this reference of reflux into the esophagus.

Based on the foregoing, applicants request withdrawal of the 35 USC 103 rejection.

Summary

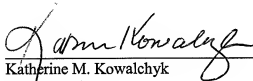
In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

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